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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,005	11/02/2001	Federico Mailland	9056-5CT	3851

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	9

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/016,005	MAILLAND, FEDERICO
	Examiner Micah-Paul Young	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 April 2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 20-40 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 20-40 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

**Acknowledgment of Papers Received:** Preliminary Amendment filed 04/10/02

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 20 – 23, 25 – 28, 30 – 38 and 40 are all rejected under 35 U.S.C. 102(b) as being anticipated by Züger (USPN 5,69,911). The claims were drawn to a method for improving the bioavailability of an ergot derivative comprising mixing said derivative with a pharmaceutically acceptable carrier. The ergot derivative is recited to be selected from the group consisting of  $\alpha$ -dihydroergocryptine and bromocriptine. The excipient was selected from the group consisting of cellulose derivatives well known in the art. The claims are also drawn to a sustained-release composition comprising the ergot derivative and other common excipients well known in the art. The claims further recite that the bioavailability of the compound is increased by 25%.

Züger teaches a sustained release combination of ergot derivatives such as  $\alpha$ -dihydroergocryptine (col. 1, lin. 55 – 60) with hydrophilic swelling agents and pharmaceutical excipients such as hydroxypropylcellulose and beeswax (col. 2, lin. 30 – 55). The reference teaches a ratio of ergot derivative to hydrophilic swelling agent of 1:0.5 to 1:2 (col. 2, lin. 57 – 58). The reference also teaches that  $\alpha$ -dihydroergocryptine is present in the formulation concentrations from 4.5 to 7.5 mg (examples). These disclosures render the claims anticipated.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 24, 29 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Züger (USPN 5,69,911) in view of Fluckiger et al (USPN 3,752,888). The claims are drawn to method of improving the bioavailability of an ergot derivative where the derivative is bromocriptine. The claims also include a composition comprising hydrophilic swelling polymers at a particular ratio to the ergot derivative.

As discussed above Züger teaches elements of the claimed invention. What is lacking is a teaching of bromocriptine as the ergot derivative. Fluckinger et al teaches a brominated ergocryptinine product (col. 2, lin. 54 – col. 3, lin 6), which can be combined with hydrophilic swelling agents and other excipients (examples).

With this in mind, it is well within the level of skill in the art to substitute similar active agents into formulation in order to achieve similar if not identical results. A skilled artisan would have been motivated to substitute the compounds of Fluckinger into the formulation of Züger in order to impart alternative therapeutic properties on the formulation. It would have been obvious to make this substitution with an expected result of sustained release formulation

comprising a brominated ergot derivative and hydrophilic swelling agents, with therapeutic properties.

***Response to Amendment***

6. The declaration under 37 CFR 1.132 filed 03/20/2002 is insufficient to overcome the rejection of claims 1 – 19 based upon 35 USC 102 as set forth in the last Office action because: a 37 CFR 1.132 declaration cannot be used to overcome a 102(b) rejection, since the rejection is based on one of anticipation and not of obviousness.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young  
Examiner  
Art Unit 1615

MP Young  
March 17, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600